"A Microwave Antenna for Medical Ablation"

Technical Field

This invention concerns a microwave antenna for medical ablation. In particular it concerns such an antenna suitable for cardiac ablation. In a further aspect it concerns a method for making such an antenna.

Background Art

The heart is composed of three types of cardiac tissue, atrial muscle, ventricular muscle and specialized excitatory and conduction tissues. The atrial and ventricular muscles of the heart are normally excited synchronously. Each cardiac cycle begins with the generation of action potentials by the sino-atrial (SA) node located in the posterior wall of the right atrium. These action potentials spread through the atrial muscle by means of specialized conduction tissue, causing contraction. The action potentials do not normally spread directly from the atrial muscles to the ventricular muscle. Instead, the action potentials conducted in the atrial musculature reach the atrioventricular (AV) node and its associated fibres, which receive and delay the impulses. Potentials from the AV node are conducted to the His-Purkinje (HIS) bundle. This structure carries the impulses to the ventricular musculature to cause their synchronous contraction following contraction of the atrial muscles.

Arrhythmia is a term used to describe irregular beating of the heart. Cardiac arrhythmias generally result from abnormal electrical connections or circuits which form within the chambers of the heart. For example, arrhythmia circuits may form around the veins or arteries.

Episodes of an abnormal increase in heart rate are termed paroxysmal tachycardia. This can result from an irritable focus in the atrium, the AV node, the HIS bundle, or the ventricles. Episodes of tachycardia may be initiated and sustained by either a re-entrant mechanism, or may be caused by repetitive firing of an isolated focus.

Atrial fibrillation occurs in the atrial of the heart, and more specifically at the region where pulmonary veins are located. It is one of the most common arrhythmias with high mortality rate. In the elderly population, those over the age of 80, it has a prevalence of around 10%. One third of all patients who have strokes are in atrial fibrillation when they get to hospital. The atrial fibrillation causes clots in the atria, which travel to the brain to cause the stroke. If a patient goes into atrial fibrillation after a heart attack, the likelihood of fatality doubles. Of all patients with atrial fibrillation the risk of a stroke or similar problem is around 5% per year if not treated.

Each year, around the globe, millions of people are affected by arrhythmias. Many can be treated and are not life-threatening, however, they still claim about 500,000 lives in the United State of America each year.

Current medical treatments rely on pharmaceutical medications which have, at best, a success rate of 50%. Furthermore, these patients may suffer adverse and sometimes life threatening side effects as a result of the medication.

Cutting the arrhythmia circuits is a successful approach to restoring normal heart rhythm. Many different cutting patterns may be implemented to cut arrhythmia circuits. Cardiac ablation involves creating a lesion by use of heat in the myocardial tissue, and has been successfully used to cut arrhythmia circuits. Prior to ablation, the electrical activation sequence of the heart is mapped to locate the arrhythmogenic sites or accessory pathways.

One obsolete ablation approach is the use of high voltage, direct current defibrillator discharges. This approach requires general anaesthesia and can rupture certain cardiac tissues.

Catheter cardiac ablation has recently become an important therapy for the treatment of cardiac arrhythmias, cardiac diarrhythmias and tachycardia. This therapy involves the introduction of a catheter into the veins and manoeuvring it to the reach the heart. An ablation system is then introduced through the catheter to position the ablation source where the tissue is to be ablated.

Radio frequency (RF) catheter ablation systems make use frequencies in the several 100 kHz range as the ablating energy source, and a variety of RF based catheters

and power supplies are currently available to the electrophysiologist. However, RF energy has several limitations including the rapid dissipation of energy in surface tissues resulting in shallow lesions and failure to access deeper arrhythmic tissue. Another limitation is the risk of clots forming on the energy emitting electrodes.

The use of optical and ultrasound energy as ablation sources has also been investigated with limited success. Microwave energy has also been proposed.

However, it has proved to be extremely difficult to treat atrial arrhythmias using catheter ablation since it is necessary to produce linear lesions sufficiently long and deep to provide an isolating channel between two conducting nodes. If an effective and continuous linear lesion is not formed the unwanted electrical signal in the heart may be able to find an alternative path. This will cause recurrence of the arrhythmia after the procedure.

Disclosure of Invention

The invention is a microwave antenna for medical catheter ablation, comprising: A transmission line having an inner conductor, an outer conductor and a dielectric insulator to provide insulation between the inner and outer conductor. An energy emitting antenna element positioned at the distal end of the transmission line to transmit microwave energy. The antenna element has an inner conductor electrically coupled to the inner conductor of the transmission line, and a sheath of dielectric insulator around the inner conductor. A conducting cap is electrically connected to the distal end of the inner conductor, and the cap surrounds a length of the sheath of insulator. The dimensions of the cap are determined to provide impedance matching between the antenna element and the transmission line.

Appropriate impedance matching not only minimises reflections, but also sets up standing waves in the antenna element that assist in producing a near-field having high power.

The particular dimensions of the metallic cap that may be determined, include one or more of:

The length of the cap

The length of the sheath of insulator that is surrounded by the cap

The radius of the cap (the inner radius is determined by the insulator)

The antenna element may be built into the end of the transmission line, and the cap may be soldered to the inner conductor of the transmission line to ensure high physical integrity to the antenna. In particular, a first length of the outer conductor may be removed from the distal end of the transmission line to create the antenna element. A shorter length of the dielectric insulator may be removed from the distal end to expose a length of the inner conductor for fixing of the cap. In this case the dimensions to be determined may further include:

The length of exposed inner conductor between the distal end of the sheath of insulator and the cap.

In one example, the antenna element may be configured with conducting rings, for instance copper or gold, spaced apart from each other along its length by slots. In particular, it may comprise insulating and conducting rings placed alternately along the length of insulating sheath. The insulating rings serve to space the conducting rings apart. An insulating ring is placed first to isolate the adjacent conducting ring from the outer conductor of the transmission line, and last to space the last conducting ring from the cap. In this configuration one or more of the following additional dimensions may be determined:

The width(s) of the conducting rings

The width(s) of the slots (insulating rings)

The length of the antenna element between the end of the outer conductor and the cap.

The conducting rings may comprise rings of outer conductor of the transmission line left in situ.

The cap may be made using a separate conducting ring.

The sizes of the conducting rings and the slots between them affect both amplitude and the phase of the microwave energy being emitted from each slot. As a result they may be selected to determine the shape of the near-field distribution. Making all the conducting rings the same size, and all the slots between them the same size, results in a uniform near field distribution along the length of the antenna element. An

optimum configuration may involve the conductive rings being twice as wide as the slots between them.

It is an advantage of this slot configuration is that the length of the antenna element can be lengthened or shortened while maintaining a uniform near-field distribution, making it ideal for creating linear lesions for the treatment of atrial fibrillation.

The dielectric loading produced by the size of the insulator surrounded by the cap may be optimized to ensure the near-field terminates at the tip of the antenna rather than at the transmission line/antenna element junction. This prevents heating of the transmission line during the ablation procedure.

By introducing non-uniformity into the slot and ring sizes, the near field can be directed forward or backward. Increasing the slot and ring sizes gradually towards the tip of the antenna makes a forward firing antenna. This can produce spot lesions useful, for instance, for treatment of tachycardia. Decreasing the slot and ring sizes gradually towards the tip of the antenna makes a reverse firing antenna. This can be useful where the tip of the antenna is in a location where no heating is required.

In an alternative example, the antenna element may be configured by being bent to form an open loop oriented such that it extends transverse to the longitudinal axis of the transmission line. This antenna is able to create a circumferential lesion, for instance, around the pulmonary vein. In this configuration one or more of the following additional dimensions may be determined:

The straight length of the sheath of insulator before bending begins.

The radius of bending between the transmission line and the open loop.

The perpendicular distance between the open loop and the beginning of bending.

The radius of the open loop

The length the cap not surrounding the sheath of insulator

The perpendicular distance between the top of the cap and the transmission line.

The shape of this antenna determines the shape of the near-field. The near-field terminates at both the tip of the antenna and the antenna element/transmission line junction. When in situ within a vein, unwanted heating of the transmission line/antenna element junction is reduced by the cooling effect of blood flow.

The antenna may further comprise a Teflon sheath surrounding at least the antenna element. This ensures electrical safety and biocompatibility.

The antenna element may be delivered to an ablation site by feeding the transmission line through a catheter.

The antenna may further comprise a temperature sensor to sense the temperature of the tissue being ablated by the antenna.

The microwave generator may deliver energy at 2.45 GHz or at any other suitable frequency.

A computer control system may be provided to monitor the ablation process and control the microwave generator.

Microwave catheter cardiac ablation offers an alternative treatment modality for patients whose heart rhythm disorders are not responsive to drug therapy, or patients who are too weak for open-heart surgery. It offers the treatment efficacy of open-heart surgery without the associated trauma and post-operative intensive care.

The microwave antenna may be used for ablation, for hyperthermia and for coagulation treatments.

One of the many advantages of tissue ablation using energy at microwave frequencies is that the microwave energy can be delivered to the myocardium without physical contact between the antenna and the myocardium.

In a further aspect the invention is a method for making a microwave antenna for medical catheter ablation, comprising an energy emitting antenna element having an inner conductor and a surrounding sheath of insulation, in use, located at the end of a transmission line. The method comprises the steps of:

forming a conductive cap at the distal end of the antenna element such that it surrounds a length of the sheath of insulator;

electrically coupling the conducting cap to the inner conductor of the antenna element; and

determining the dimensions of the cap to provide impedance matching between the antenna element and the transmission line.

Brief Description of the Drawings

Two examples of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1(a) is longitudinal section through a coaxial ring slot array antenna.
Figure 1(b) is an end view of the antenna of Figure 1(a).
Figure 1(c) is an exploded diagram of the antenna of Figure 1(a).
Figure 2(a) is a graph showing the normalized near-field across each corresponding slot of the antenna of Figure 1.
Figure 2(b) is a graph showing the reflection coefficients of the antenna of Figure 1.
Figure 2(c) is a graph showing the normalized SAR level for the antenna of Figure 1.
Figure 2(d) is a plot showing the E-field vector of the antenna of Figure 1.
Figure 2(e) is a graph of the measured and simulated reflection coefficient of the antenna of Figure 1.
Figure 2(f) is a graph showing the measured and simulated input impedance of the antenna of Figure 1.
Figure 2(g) is a graph showing the measured temperature distribution of the antenna of Figure 1.
Figure 2(h) is a graph showing the measured temperature at various depths using various power settings.
Figure 2(i) is a graph showing maximum temperature obtained at various depths for different power levels.
Figure 3(a) is a pictorial diagram of a parallel loop antenna.
Figure 3(b) is a top elevation view of the antenna of Figure 3(a).
Figure 3(c) is an end elevation view of the antenna of Figure 3(a).
Figure 3(d) is a right elevation view of the antenna of Figure 3(a).
Figure 4(a) is a plot of the E-field vector in the X-Y plane for the antenna of Figure 3.
Figure 4(b) is a plot of the E-field vector in the Y-Z plane for the antenna of Figure 3.

Figure 4(c) is a graph of the effect of loop radius, on the reflection coefficients of the antenna of Figure 3.

Figure 5 is a flow chart illustrating the steps involved in creating lesion.

Figure 6 is a block diagram showing ablation modalities.

Figure 7 is a flow chart for the Fixed-Power Fixed-Time (FPFT) ablation modality.

Figure 8 is a flow chart for the temperature modulated microwave ablation modality.

Figure 9(a), (b) and (c) are graphs of the power delivery waveforms for three different ablation modalities.

Figure 10 is a graph of temperature and power waveform for the C/V duty cycle pulsed ablation modality.

Figure 11 is a graph of temperature and power waveform for the Temperature Modulated pulsed ablation modality.

Best Mode for Carrying Out the Invention

The Coaxial Ring Slot Array (CRSA) Antenna

Figure 1 shows the configuration of the coaxial ring slot array (CRSA) antenna 10 for cardiac ablation. The antenna 10 has a coaxial cable transmission line 11 and an antenna element 12 formed at the distal end of the transmission line 11. The coaxial cable comprises an inner conductor 13, an outer conductor 14 and a Teflon dielectric insulator 15 which provides insulation between the inner 13 and the outer 14 conductors. The insulator 15 has a diameter of about 3 mm, and the conductors about 0.91 mm.

The antenna element 12 is constructed out of the distal end of the transmission line by first removing the outer conductor 14 of the coaxial cable for the length $L_l+L_f+L_{tx}$, exposing a sheath 16 of insulator 15. At the distal end of the antenna element 12 a short length L_{tx} of the Teflon insulation sheath 16 is removed exposing an equally short length 17 of the inner conductor 13. Copper rings 18 are made from copper tubes with diameter r_{ho} and the rings have a width of R_w. Similar dielectric spacer rings 19 are made out of Teflon material of width S_w. The dielectric spacer rings 19 are shown only in Figure 1(c) for the sake of simplicity.

A first dielectric spacer 19 is slid onto the exposed insulator followed by the first copper ring 18. This electrically isolates the copper ring 18 from the outer

conductor 14. The procedure is then repeated until all the dielectric spacers 19 and copper rings 18 are in place, and all the copper rings 18 are isolated from each other.

When the last, insulating, ring has been slipped onto the distal end of the antenna element, the Teflon sheath extends beyond the rings for a short distance L_r a 'perturbation distance'. To seal off the distal end, hollow copper cap 20 is located partly surrounding the Teflon sheath but with its distal end extending beyond the end of the Teflon sheath. Then both the distal end of the cap 20 and the exposed length 17 of inner conductor 13 are pre-heated with soldering gun, and solder is then melted within the hollowed section 21 between the ring and the inner conductor. When the solder cools, it fuses the inner conductor together with the cap and the cap is partially filled with dielectric insulator. The cap 20 is integrated onto the end of the inner conductor. Between the end of the outer conductor 14 and the cap 20 there is an antenna element 12 comprising copper rings separated by radiation emitting slots.

The cap 20 may be made using one of the copper rings

The antenna is constructed using TFLEX-402 flexible coaxial cable. It can be seen in Figure 1(a) that the radius of the rings 18 and 19 is the same as the radius of the outer conductor of the coaxial cable. This radius of the cap is also seen to be the same as the outer conductor in this Figure. This allows easy insertion of the antenna into the heart via catheters. Figure 1(b) shows that the cap radius may be larger than the cable, as this is a variable dimension.

A Teflon sheath (not shown) encapsulates the entire antenna 12 to finish construction.

Figures 1(a) and 1(b) show the constitutive parameters for this antenna:

Static Dimensions

- r_i: Radius of the inner conductor of the coaxial cable,
- r_t: Radius of the PTFE dielectric,
- r_o: Radius of the outer conductor of the coaxial cable,

Variable Dimensions

- r_{hc}: Radius of the cap,
- S_w: Width of the slots (insulating rings) between the copper rings,

- R_w: Width of the copper rings,
- L_{ix}: Length of the exposed inner conductor between the distal end of the sheath of insulator and the cap,
- L_t: Length of extension of the sheath of insulator that is surrounded by the cap,
- L_l: Length of the antenna element between the outer conductor and the cap,
- C_L: Length of the cap.

For any given length on antenna element (determined by the length of the lesion required), another variable parameter is the number of rings, N, which makes $N+1$ slots in total. The number of rings and slots must be selected in order to achieve a uniform near field distribution. The dimensions of the cap are determined for each length and ring and slot combination.

Figure 2(a) shows excitation from multiple sources has been achieved. The normalized near-field distribution across each slot in the antenna also shows only small variation in the magnitude of the near-field distribution along the length of the antenna element.

The spacing between the slots determines the phase of the microwave radiation, and therefore its primary direction. Uniform near-field amplitude and phase distributions results in coherent radiation emission in the near-field, thus forming a lesion of linear shape.

Iterative Procedure

An iterative procedure is used to determine the dimensions of the constitutive parameters of the CRSA antenna. Firstly, the iterative procedure is used to obtain the optimum dimensions for the slots and rings for the CRSA antenna. The antenna is to be used for creating linear lesions, the length of the CRSA antenna is adjusted to suit the length of the lesion; in this example the length of the antenna is selected to be 20mm.

Figure 2(b) shows the effect changes of the slot and ring sizes have on the reflection coefficients of the CRSA antenna. Five different combinations have been used in order to obtain the optimum slot and ring sizes in order to achieve lowest antenna return loss. The combinations are shown in Table 1.

Table 1: Slot and ring combinations used to obtain the reflection coefficient of CRSA antenna shown in Figure 2(b)

	Ring Size (mm)	No. Rings	Slot Size (mm)	No. Slots
Combination 1	10	1	4	2
Combination 2	4	2	4	3
Combination 3	1	9	2	10
Combination 4	1	10	1	11
Combination 5	2	5	1	6

From Figure 2(b) it can be seen that a CRSA antenna with two large slots and one large ring (combination 1) is not an efficient radiator as indicated by its high energy reflection at 2.45 GHz. As the number of rings and slots increases, it is possible to lower the reflections of the CRSA antenna to a minimum at 2.45 GHz. By using an iterative procedure, the optimum widths for the slots and rings are found to be 2mm for the rings and 1mm for the slots. This is shown in Figure 2(b) as combination 5 which clearly gives the lowest reflection at 2.45 GHz. It should be pointed out here that the cap dimensions are adjusted, after the dimensions of the slots and rings have been determined, to take account of the final dimensions of the slots and rings. The dimensions of the cap for each of the five slot-ring combinations are shown in Table 2.

Table 2: Cap dimensions (in mm)

	Cap Length (C_L)	Dielectric Length in the Cap (L_t)	Exposed Inner Conductor Length in the Cap (L_{ix})	$L_t + L_{ix}$
Combination 1	4	2	1	3
Combination 2	4	1	2	3
Combination 3	4	1	3	4
Combination 4	3	1	1	2
Combination 5	4	2	1	3

Figure 2(c) shows the normalized specific absorption rate (SAR) level of the CRSA antenna of Figure 2 (d). It can be seen that the SAR level remains almost substantially flat across the entire length of the CRSA antenna.

This flat characteristic is also seen when the flow of the near-field, that is the E-field vector, is plotted, see Figure 2(d). It can be seen that the flow of E-field across each of the slots is very smooth thereby generating uniformly distributed SAR. It should also be pointed out that by optimizing the size of dielectric loading inside the cap at the end of the CRSA antenna it is possible to make the E-field terminate at the tip of the antenna rather than to the coaxial cable/antenna junction. This ensures that the coaxial cable will not be unnecessarily heated during the ablation procedure.

Figure 2(e) shows the simulated and measured reflection coefficients of the CRSA antenna. It is clear that, with optimized slot, ring and dielectric cap dimensions, at the operating frequency of 2.45 GHz the CRSA antenna give very low reflections. This indicates that the CRSA antenna can couple microwave energy efficiently and effectively into the myocardium. Another characteristic of the CRSA antenna shown in this Figure is that it exhibits wide 3dB impedance bandwidth. This is important where the dialectric properties of the surrounding tissue may change with temperature, causing changes in antenna performce. By ensuring that the CRSA antenna has wide 3dB impedance bandwidth, these changes will not decrease the efficacy of the CRSA antenna.

Figure 2(f) shows the simulated and measured input impedance of the CRSA antenna across frequency span of 1 to 5 GHz. As can be seen, the input impedance of the CRSA antenna at 2.45 GHz is very close to the source impedance of 50 Ω. Since the optimized CRSA antenna matches the input impedance of the microwave generator, it is capable of delivering microwave energy without much reflection. The final optimized dimensions for the CRSA antenna are listed in Table 3.

Table 3: Final CRSA antenna parameter dimensions in mm.

Parameter	r_i	r_t	r_o	r_{hc}	S_w	R_w	L_{tx}	L_l	L_t	C_L
Dimension	0.255	0.816	1.071	1.1	1	2	1	20	2	3

Thermal Analysis of the CRSA Antenna

Figure 2(g) shows the spatiotemporal thermal distribution of the CRSA antenna with input power of 80 watts. It can be seen that after 20 seconds of applying microwave energy, the temperature reached by probe A is 80 degrees. This indicates

that CRSA is capable of depositing microwave energy effectively into the myocardium thereby reducing the duration of ablation.

Figure 2(h) shows the plot of measured temperature at various depths into the myocardial tissue using different power settings while the duration is 30 seconds. It can be seen that with an applied power of 100 watts (the diamond line), temperature reached close to 85°C at the surface of the tissue. The temperature drops gradually as the depth of the tissue is increased. At 10 mm deep into the myocardium, the temperature obtainable using 100, 80, 60, 40 and 20 watts are 59°C, 57°C, 55°C, 48°C and 39°C respectively. From this power-temperature profile, it can be seen that the input power of 60 watts is adequate for the CRSA antenna to achieve irreversible transmural lesions. Also, the radiation will not unnecessarily heat surrounding tissues.

From the same Figure 2(h), it is clear that there is a difference between the temperatures obtainable in the tissue as the power is increased from 40 to 60 watts. Due to the excellent impedance matching, a 50% increase in applied power translates to almost 15°C increase in temperature at the myocardial tissue surface, and 8 °C increase at 10mm deep into the tissue.

This type of thermal characteristic of an antenna is desirable because it means that the CRSA antenna is suitable in a wide range of thermal therapy applications. Since the thermal profiles of applied power of 60 watts or greater are above 55°C, high power can be applied to the CRSA antenna to create necrotic tissues while lower power settings (40 watts or lower) can be applied to the CRSA antenna for hyperthermia applications.

Finally, Figure 2(i) shows the temperature recorded at 1, 4, 7 and 10 mm into the myocardial tissue for various power settings. Again, with 60 watts, the temperature recorded is already exceeding 55°C which indicates 60 watts is the optimum power setting for CRSA antenna for tissue necrosis.

Field Variation

The ability to generate uniform excitation across uniformly spaced slots and metallic rings is exploited further to define the shape the near-field distribution produced by the CRSA antenna. By introducing non-uniformity into conducting and insulating ring sizes the E-field level towards the tip of the CRSA antenna can be

enhanced while minimizing the E-field level near the antenna/cable junction by using narrow slot and ring sizes there. The slot and ring sizes are increased gradually as it approaches the tip of the CRSA antenna. This, in-effect, makes the CRSA antenna a forward firing antenna.

The opposite effect on the near-field distribution can also be achieved by reversing the slot and ring sizes on the CRSA antenna. That is, the width of the slots and rings near the antenna/cable junction is made larger and their sizes gradually decrease as they approach the tip of the antenna. This makes a reverse firing antenna.

The possibility of adjusting the near-field distribution by changing the slot-ring compositions makes the CRSA antenna useful for various types of ablation. The forward firing antenna is useful for creating short linear lesions as well as spot lesions used in the treatment of ventricular tachycardia. The reverse firing antenna is useful for producing lesions near the antenna/cable junction but not towards the tip of the antenna, this can be useful for instance where the tip of the antenna is extended to areas where heating should be minimized. An example of this is where the tip of the antenna may be extended over the tricuspid valve during the ablation of the atriventricular node for the treatment of atrial fibrillation.

The Parallel Loop (PL) Antenna

The configuration of the parallel loop (PL) antenna 30 is shown in Figures 3(a) to 3(d), the same reference numerals have been used as in Figure 1 to identify the corresponding features. This antenna is used to create circumferential lesions around the pulmonary vein. It is called the parallel loop antenna because the center axis 31 of the loop antenna section is parallel to the axis 32 of the coaxial cable.

The constitutive parameters of a PL antenna are:

Static Dimensions

- r_i: Radius of the inner conductor of the coaxial cable,
- r_i: Radius of the PTFE dielectric,
- r_o: Radius of the outer conductor of the coaxial cable,

Variable Dimensions

- r_{hc}: Radius of the cap.

- D_T: The perpendicular distance between the top of the cap and the transmission line.
- D_2: The perpendicular distance between the open loop and the beginning of bending.
- D_3: The straight length of the sheath of insulator before bending begins.
- L_{lx}: Length of the exposed inner conductor between the distal end of the
- L_l: Length of the sheath of insulator that is surrounded by the cap.
- D_5: The length the cap not surrounding the sheath of insulator ($D_5 = D_T - D_4$).
- L_l: Length of the antenna element between the outer conductor and the cap,
- C_l: Length of the cap.
- L_{lr}: The radius of the open loop.
- B_r: The radius of bending between the transmission line and the open loop.

The variable parameters are determined using an iterative procedure as before.

The loop antenna is designed to creates a near-field that surrounds the entire loop element, but extends very little along the coaxial cable section. This feature enables the loop antenna to create a circumferential lesion along the wall of the pulmonary vein.

Evidence of the confinement of the near-field to the loop element section of the PL antenna is shown on the vector plot of the E-field flow, see Figure 4(a) and (b). On the *X-Y* plane it can be seen that the E-field emitted from the loop section of the PL antenna uses the cap as the return path.

Apart from the loop antenna feeding section, most of the areas surrounding the loop antenna are being exposed to same level of SAR. This is made possible due to the fact that the areas surrounding the loop antenna section are very evenly illuminated by E-fields.

The areas immediate surrounding the PL antenna has very high level of SAR where most of heating occurs. The SAR value decreases rapidly as the distance away from the loop section of the PL antenna increases and that by the time the E-field reaches the point furthest away from the PL antenna the SAR value has already dropped to less than 50% which is not sufficient to create any irreversible damage to

the tissue under the short time duration used for ablation. This is a desirable safety feature of the PL antenna as the areas immediate surrounding the pulmonary vein are heated, the tissue outside of the pulmonary vein, although will also be heated, but irreversible damage on the tissues outside of the pulmonary vein will not be made.

On the other hand, the near-field emitted from the bending section of the loop antenna uses the coaxial cable/antenna junction as the return path as intended. Due to the complexities of the PL antenna, two return paths are required in order to confine the near-field to the loop section of the PL antenna. Although the use of cable/antenna junction as the return path for parts of the near-fields can cause hot spots to form around the cable/antenna junction area, the rate of blood flow in the pulmonary vein is high enough to provide adequate cooling to the PL antenna.

Iterative Procedure

In order to produce such results an iterative procedure is used to optimize the PL antenna.

There are many variable constitutive parameters of the PL antenna, and all can be optimized. In order to accelerate the optimization procedure, the iterative optimization of the PL antenna is separated into two sections:

Firstly, the radius of the open loop L_{lr} is optimized. The reflection coefficient of various loop sizes are obtained, see Figure 4(c) which plots the reflection coefficient of the PL antenna based on the radius of the open loop. From Figure 4(c) it is clear that the size of the loop has strong effect on the reflection coefficient of the loop antenna. There are two local minima, but since 16mm diameter is too big for insertion into the pulmonary vein, L_{lr} is selected to be 9 mm.

Once the optimum dimensions for the loop have been obtained, the iterative procedure then proceeds to optimize the bending radius B_r based on the dimensions obtained for the loop section. The cap of the PL antenna is then optimized. Other dimensions such as the amount of exposed insulation before bending D_3, and the amount of insulation and inner conductor in the cap have a direct affect on the return loss of the antenna, and are also optimized. The distance away from the cable/antenna junction before the bending of the loop section of PL antenna starts, is bounded by construction constraints to be no less than 3 mm and no more than 10mm.

Microwave Ablation System Hardware And Software Development

Figure 5 shows the process for creating lesions. First of all, microwave energy is generated 50 by a microwave generator. The energy is then delivered 52 to the myocardial tissue by microwave antennas 12 and coaxial cable. Part of the delivered energy is absorbed 54 by the myocardial tissue and part of the delivered energy is reflected or lost in the surrounding materials. The energy absorbed by the tissue then causes the tissue temperature to rise 56 to a point where tissue necrosis occurs 58 and subsequently the lesions are formed.

Interface Card

An interface card links the remote control interface, see Table 4, of the microwave generator to a notebook computer to automate monitoring of forward/reflected power, ablation duration and switching the generator on and off. A serial interface is used to connect the microwave generator to a notebook computer to be remote controlled.

Table 4 Remote control interface pin assignment.

Pin Number	Description
1	Remote external interlock. (High = Remote Control)
2	External interlock chain status. (High = On)
3	Operation Status. (High = In operation)
4	Operation/Standby status. (Maintained High = Operation)
5	Reflected power monitor. (0 to 5 volts = 0 to 250 watts)
6	Forward power set. (0 to 5 volts = 0 to 250 watts)
7	Forward power monitor. (0 to 5 volts = 0 to 250 watts)
8	Remote reflected power input.
9	Remote external interlock.
10	Circuit ground.
11	Circuit ground.
12	Circuit ground.
13	Circuit ground.
14	Circuit ground.
15	+ 15V DC*

In order to protect the notebook computer from power surges which may be caused by the reflected power from the load, the notebook computer is isolated from the microwave generator using opto-isolator transistors on the digital data line and the two analog forward and reflected power monitoring lines.

In order to provide enough current to drive the opto-isolators as well as the multiplexer switch in the interface card, +15 volt DC is tapped from a pin of the microwave generator. A voltage regulator is used to provide a regulated +5 volt DC to supply to the opto-isolators and the multiplexer switch.

The interface card also provides a RS-232 terminal to connect to the temperature measurement system for the recording and monitoring of temperatures during ablation.

A graphical user interface is provided for the notebook computer.

Control and Monitoring Software

Figure 6 shows the structure of the microwave ablation control and monitor software. The way microwave energy is delivered to the myocardium is dependent on which ablation modality the cardiologist chooses.

The first ablation modality 60 requires the microwave generator to output a predefined level of energy for a predefined time.

Referring to Figure 7, the power output is set. An analog meter displays the actual power being delivered. To increase the flexibility of the power delivery mode, the power can be increased or decreased in real time. Even though the microwave generator is capable of generating 250 watts, the maximum power output is electronically limited to 100 watts for safety reasons.

The ablation duration is then set 72, in seconds. Similar to the power setting, the total ablation duration can be increased or decreased in real time during ablation depending on the cardiologist's decision.

Once the power and time are defined, the Run/Stop toggle switch can be pressed 74 to initiate the pre-ablation checking sequence 76. The pre-ablation check sequence consists of checking if the power setting is higher than 80 watts 78 and that if

the time is longer than 60 seconds 80. If this combination is detected, then an alarm will sound and the cardiologist is required to confirm the entered power/time combination 82. If the cardiologist confirms 84 that the power/time settings are correct, then the program proceeds and the ablation procedure is initiated. A real time display is provided of the tissue temperature during ablation. However, on the other hand, if no confirmation is received the program is terminated 86.

Once the program enters the ablation stage 88, the program continues to execute until the preset ablation duration is reached 90 and then the program, hence the ablation procedure, is terminated 92. It should be pointed out that the Run/Stop switch also acts as an emergency stop switch which is electronically-wired to the space bar.

Once the ablation procedure is terminated, the recorded temperature, together with power and time settings, are saved in the local hard disk of the notebook computer for record keeping and further analysis if necessary.

During ablation, the recorded temperature is used to monitor the tissue temperature. If the temperature is over a preset level, even if the ablation time is not reached, the program will terminate hence stopping the ablation procedure. This is a necessary safety condition so that the tissue temperature is no overheated in order to avoid tearing and charring of the myocardial tissue.

The second modality 61 delivers energy pulses to the myocardium based on either a fixed or variable duty cycle.

A digital temperature readout is provided. The duty cycle for the power delivery can be set by entering appropriate time duration for ON time and OFF time. During the ON-time, microwave energy is delivered to the myocardium and during the OFF-time the microwave generator is in standby mode. The pre-ablation check sequence is also used before the pulsed ablation procedure begins.

The third modality 62 modulates the delivered energy within upper and lower bound of desirable tissue temperature.

Figure 8 shows the control algorithm. The upper and lower temperatures represent extra control parameters that are required to be entered 100 to achieve this modality. The software also continuously monitors 102 and displays 104 the tissue temperature. During ablation 106 if the tissue temperature is monitored 108 to see

whether it has approached or exceeded the upper temperature threshold (UTT). If so, an instruction to stop 110 the microwave energy delivery is issued to the microwave generator. When the instruction is received, the microwave generator is switched to stand-by mode. When the tissue temperature falls below the lower temperature threshold (LTT) 112, an instruction to begin energy delivery again is sent to the microwave generator. When this instruction is received, the generator begins to deliver microwave energy to the myocardium. This cycle continues until the end of ablation time is reached.

Lastly, the fourth 63 allows the cardiologist to have full manual control. Under this energy delivery mode, the microwave generator can be operated either through the front panel or through the remote control notebook computer. Also, the pre-ablation check is disabled. During ablation, however, the temperature data are still recorded and stored for record keeping and post processing purposes.

Effect on Lesion Sizes Due to Different Ablation Modalities

Figure 9 shows the power delivery waveforms associated with ablation modalities. The power delivery waveform for manual mode is not shown because the power being delivered to the myocardium is dependent on the cardiologist operating the ablation system.

Figure 9(a) shows the power waveform for the Fixed-Power Fixed-Time (FPFT) ablation modality. It is clear that for FPFT ablation modality, the power is delivered to the myocardium for a specified time. This is the most common type of ablation modality used because it can be used to deliver high amount of energy in a very short duration to achieve a deep lesion at the cost of wider lesion. This type of ablation modality is useful if large volume of tissue is required to be ablated.

In order to reduce the width of the lesion, areas in the tissue not immediately heated by microwave energy should be allowed to be cooled. One way to achieve this is to introduce a series of OFF periods during energy delivery as shown in Figure 9(b). The temperature and power delivery waveform for the C/V duty cycle pulsed ablation modality. From Figure 10 it can be seen that during the initial power delivery period, the temperature is allowed to rise until it reaches the upper limit of the tissue temperature (UTT) which is preset at 90 ^{o}C. Once the preset tissue temperature has been reached, the duty cycle starts and pulsing of microwave energy is initiated. The

power waveform shown in Figure 9(b) has a duty cycle of 5:3, that is, the microwave generator is operating at 5 seconds ON and 3 seconds OFF. Note that the preset temperature in this ablation modality can only be changed by physically modifying the program code. From Figure 10, it is clear that the tissue temperature is allowed to be cooled, hence the temperature drop, for the period that the microwave generator is in standby (OFF) mode. This has the effect that the tissues not immediately heated by microwave energy are not heated too much thus reducing the lesion width growth caused by heat conduction. The duty cycle of energy delivery pulse can be made constant, that is 50% ON time and 50% OFF time or variable such as the one shown. Although the pulsed power delivery mode is able to reduce the width of the lesion, this is achieved at the cost of longer ablation duration. This is due to the fact that in order to achieve same lesion depth as the ones achievable using the FPFT ablation modality, longer time is required.

Figure 9(c) shows the power delivery waveform of the Temperature Modulated Pulsed Ablation Modality. Similar to the power delivery waveform shown in Figure 9(b), microwave energy in this modality is delivered by pulsed method. The difference between the C/V duty cycle pulsed modality and the temperature modulated modality is that the duty cycle for the pulse train is not required. Instead, the upper and lower threshold tissue temperature (UTTT and LTTT respectively) are defined. This is shown in Figure 11. During the initial power delivery stage, the temperature is allowed to rise until the UTTT value then the microwave generator enters the standby mode thereby stopping the power delivery. Once the notebook computer detects that the temperature has fallen below the LTTT value the microwave generator is switched back to ON position and the power delivery begins again.

The advantage of using the temperature modulated power delivery modality is that the power being delivered to the myocardial tissue can be made to adapt the state of tissue temperature. For example, due to the high thermal energy produced by the initial microwave irradiation, when the temperature reached the UTTT state the time in which the microwave generator is in OFF status is longer. When the tissue temperature falls near or below the LTTT state, the time in which microwave generator is in ON status is adjusted automatically in order to keep the tissue temperature variation within the UTTT and LTTT state.

If the UTTT is set at 90°C, such as the one shown in Figure 10, then ablation takes affect. If the UTTT is set at around 45 °C, then this system can be utilized in applications such as hyperthermia for cancer treatment. Also if UTTT and LTTT values are made close together, then the microwave generator can be controlled to deliver power which will maintain the temperature within the temperature bounded by UTTT and LTTT. This is not possible with the other types of ablation modality.

Another advantage of this method, over the other methods discussed previously, is that the power is delivered dependent on the cooling conditions of the myocardial tissue. If some how the cooling of the myocardial tissue is increased, the microwave generator will be in the ON status much more than in the OFF status. On the other hand if the cooling of the tissue is hindered, then the microwave generator will be in the OFF status longer than in the ON status. When the temperature difference between the UTTT and LTTT is reduced, using the temperature modulated power delivery modality; the tissue temperature can be maintained for a preset time.

Table 5 shows the lesion sizes obtained using the three power delivery modes.

Table 5: Lesion comparisons for the three power delivery modality.

Delivery mode/Duration	Depth (mm)	Width (mm)	Surface Area (mm^2)	W:D
FPFT 80W 30sec	7.7	10.9	76.9	1.5
C/V Pulse 80/80	6.5	6.5	65	1
TM Pulse 80/90	6.8	5.7	73	0.84

To achieve large lesion size in both depth and width dimensions, the FPFT is the best method. However, as shown in the width to depth (W:D) ratio column, the FPFT also has largest W:D ratio meaning that the lesion generated using the FPFT method is much wider than it is deep. This type of power delivery modality would be very well suited for ablation in the ventricle where large volume of arrhythmogenic tissues are require to be ablated.

On the other hand, the W:D ratio of the C/V duty cycle pulsed (C/V pulse) ablation modality, a width to depth ratio of 1 can be achieved thereby reducing the unnecessary injury to the tissues surrounding the arrhythmogenic tissue. This, however, is achieved at the cost of longer ablation duration.

The temperature modulated pulsed (TM Pulse) ablation modality took the longest time to achieve a 7mm deep lesion. However, it also has the lowest width to depth ratio indicating that the lesion generated using the TM Pulse power delivery modality is deeper than it is wide which is perfectly suited for ablation in the atrium where the tissues surrounding the arrhythmogenic tissue is scarce and should be preserved.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.